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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/043,322	01/14/2002	Riichiro Abe	9511-087-27	6656

7590 01/26/2005

Supervisor, Patent Prosecution Services
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EXAMINER

YAEN, CHRISTOPHER H

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 01/26/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/043,322

Applicant(s)

ABE ET AL.

Examiner

Christopher H Yaen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 November 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12, 14-16 and 18-23 is/are pending in the application.
- 4a) Of the above claim(s) 1-11 and 20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 12, 14-16, 18, 19 and 21-23 is/are rejected.
- 7) ☒ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Re: Abe K. et al
Priority Date: 12 January 2001

1. The amendment filed 11/15/2005 is acknowledged and entered into the record. Accordingly, claims 13 and 17 are canceled without prejudice or disclaimer, and claims 21-23 are newly added.
2. Claims 1-12, 14-16, and 18-23 are pending, claims 1-11, and 20 are withdrawn as being drawn to a non-elected invention.
3. Claims 12,14-16,18-19, and 21-23 are examined on the merits.
4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Objections

5. Claim 16 is objected to because of the following informalities: claim 16 is dependent on claim 13 which is now canceled.

Appropriate correction is required.

Claim Rejections Maintained - 35 USC § 112, 1st paragraph

6. The rejection of claims 12,14-16, 18-19 and now newly added claims 21-23 as lacking written description under 35 USC § 112, 1st paragraph is maintained for the reasons of record. Applicant argues that the specification provides sufficient disclosure of the terms "cells" and "tumor antigen". In additional, applicant argues that the terms are widely used and well recognized in the art, such that one of skill in the art would be

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able to recognize what the meaning of the term would encompass. Applicant's arguments have been carefully considered but are not deemed persuasive to overcome the rejection of record. The claims are drawn to a cellular composition comprising isolated generically any cell, an anti-MIF antibody, and any tumor antigen. The issue in this case is not whether one of skill in the art would recognize the terms as claimed, but rather whether one of skill in the art would recognize that the applicant was in full possession of the invention as claimed. In this case the applicant claims a genus of cells and tumor antigens. The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus. See *Eli Lilly*, 119 F.3d at 1568, 43 USPQ2d at 1406.

In the instant case, applicant has not taught sufficient representative species of either cells or tumor antigens as claimed, nor has the applicant taught any identifying characteristics that would help one of skill in the art distinguish their product from others in the art. The specification has only specifically taught or disclosed to those of skill in the art a cellular composition comprising CD8⁺ T-cells, an anti-MIF antibody, and a tumor antigen that is derived from a thymoma. A "representative number of species" means that the species which are adequately described are representative of the entire

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genus. Thus, when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus. The disclosure of a single species of a cell or a tumor antigen is not extensive enough or is not representative of the broad genus of any cell and any tumor antigen claimed, because there are many types of cells and tumor antigens that differ structurally and functionally. Therefore, one of skill in the art would not be able to recognize that the applicant was in possession of the broad genus of cells and tumor antigens claimed at the time of filing. Therefore, the rejection of claims under 35 USC 112, 1st paragraph is maintained for the reasons of record.

This rejection now also applies to newly added claims 21-23 for essentially the same reasons. Newly added claims 21-23 are drawn to a cellular composition comprising generically any immune cells and any cancer cell incubated with an anti-MIF antibody. The specification has only provided sufficient written description for CD8⁺ T-cells and tumor cells of thymoma origin and thus this disclosure is insufficient to represent the broad class of any immune cell and any tumor cell claimed because of the widely varying structures represented by each.

All other rejections are withdrawn in view of the applicant's amendments and arguments thereto as set forth in a paper filed 11/15/2004.

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Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher H Yaen whose telephone number is 571-272-0838. The examiner can normally be reached on Monday-Friday 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Christopher Yaen
Art Unit 1642
January 18, 2005


GARY NICKOL
PRIMARY EXAMINER